

Remarks

This response reiterates the remarks that were previously submitted in the Amendment and Response filed February 14, 2005, which was not entered, and further addresses the Examiner's comments as set forth in the March 30 Advisory Action. Applicants appreciate the courtesy extended to Applicant's agent, Angela Dallas Sebor, during the informal telephone conference with the Examiner on April 14, 2005, to clarify the further rejection of Claim 75.

Claims 71-74 have been deemed in condition for allowance.

Claims 65-68 and Claim 76 have been canceled without prejudice to or disclaimer of the subject matter disclosed therein.

As suggested by the Examiner, Claim 69 has been amended to be an independent claim and to incorporate the limitations of base claim 65.

Claim 70 has been modified in response to the March 30 Advisory Action to add the appropriate status identifier.

Claim 74 and 75 have been amended to read "said at least 6 amino acid sequence" as suggested in the March 30 Advisory Action. In addition, Claim 75 has been amended as set forth in the February 14 Amendment and Response to clarify the language of the claim. Specifically, the hypersensitive response has been defined as an immediate or delayed-type hypersensitivity response. In addition, the limitation of "an animal known to be hypersensitive to a protein" has been changed to "an animal previously exposed to a protein". Support for these changes can be found in the specification, for example, on page 1, lines 10-22, and page 41, lines 3-23, through page 46, line 18, with particular reference to page 46, lines 12-18.

Rejections Under 35 U.S.C. §112, Second Paragraph – Indefiniteness

The Examiner has rejected Claims 65-68, 70 and 75 for lack of indefiniteness.

While Applicants believe the subject matter of these claims was adequately defined, in the interest of expediting prosecution, Claims 65-68 have been canceled. Claim 70 has been amended to depend from newly amended Claim 69. None of the rejected limitations have been incorporated into any of the amended Claims. Therefore, the rejection as applied to Claims 65-68 and Claim 70 is moot.

Claim 75 has been rejected as being indefinite for the recitation of “hypersensitive response” and “an animal known to be hypersensitive”. The Examiner states it is unclear how one of skill in the art determines hypersensitive responses from non-hypersensitive responses. Further, the Examiner states it is unclear how one skilled in the art determines those animals that are considered to be “known to be hypersensitive” from those that are not known.

Applicants have amended the Claims to clarify the language of Claim 75. Specifically, the term “hypersensitive” has been changed to “immediate or delayed-type hypersensitivity”. Applicants contend the ability to measure or determine immediate or delayed-type hypersensitivity responses is within the abilities of one skilled in the art. Furthermore, the various types of hypersensitivity responses are described in detail in *Janeway et al*, which was incorporated by reference on page 1 of the specification; see, for example, lines 17-22. Similarly, the term “an animal known to be hypersensitive” has been changed to “an animal previously exposed”. The use of this language parallels that of the specification, for example, page 1, lines 14-17. Applicants believe such terminology would be clear to one skilled in the art.

New Rejection Under 35 U.S.C. §112, First Paragraph- New Matter

In the Advisory Action mailed from the USPTO on March 30, 2005, the Examiner states that while the specification supports a hypersensitive response that is an immediate or delayed-type hypersensitivity response, he could not find support in the specification for an epitope of SEQ ID NO:62 that induces an immediate or delayed-type hypersensitivity response in an animal previously exposed to SEQ ID NO:62. The Examiner states that therefore, the specification does not support this recited limitation.

Applicants believe the specification does provide support for the recited limitation. The specification, for example, page 1, lines 14-17, defines the term “hypersensitivity” as “a state of altered reactivity in which an animal, having been previously exposed to the compound, exhibits an allergic response the compound upon subsequent exposures”. The salient point is that hypersensitive reactions occur upon *subsequent* exposure of an animal to a compound. Therefore, by definition, any compound inducing a hypersensitivity response must be doing so in an animal previously exposed to the allergen. The term compound has perhaps been considered by the Examiner to be

somewhat generic, but one of skill in the art will clearly recognize that compounds that act as allergens and can induce an immediate or delayed-type hypersensitivity response include proteins or peptides, and indeed, the present specification is directed to ectoparasite saliva proteins that can induce hypersensitive responses in an animal.

Furthermore, the specification clearly discloses the induction of a hypersensitivity response by ectoparasite saliva proteins, such as SEQ ID NO:62 (see for example page 41, lines 3-23, through page 46, lines 1-24). While the specification does not disclose, verbatim, the use of SEQ ID NO:62 to induce a hypersensitive response, the cited sections clearly describe tests for measuring the ability of a compound to induce a hypersensitivity response (*e.g.*, by a skin test, where the ectoparasite saliva protein is administered and a hypersensitivity reaction is detected, for example, by identifying wheal formation). The specification clearly states that suitable formulations to use in such testing include *ectoparasite saliva proteins of the instant invention, including proteins having an amino acid sequence listed in the Sequence Listing or homologues thereof* (see, for example, page 46, lines 12-15). Therefore, since SEQ ID NO:62 is an ectoparasitic saliva protein of the instant invention, since a fragment of SEQ ID NO:62 is a homologue of SEQ ID NO:62, and since proteins of the instant invention can be used to induce a hypersensitivity response, the specification therefore supports the use of SEQ ID NO:62 or a fragment thereof to induce a hypersensitivity response. Furthermore, since a hypersensitivity response, by definition, occurs in an animal previously exposed to a compound, the specification therefore supports the use of SEQ ID NO:62 to induce a hypersensitivity response in an animal previously exposed to SEQ ID NO:62.

In view of these amendments, Applicants request withdrawal of the indefiniteness rejections.

Rejections Under 35 U.S.C. §112, First Paragraph- New Matter

The Examiner has rejected Claims 68 and 76 for introducing new matter into specification and claims. Applicants note Claims 68 and 76 have been canceled rendering this rejection moot.

Rejections Under 35 U.S.C. §112, First Paragraph- Written Description

The Examiner has rejected Claims 65-68 and Claim 70 for lack of written description. While Applicants believe the subject matter of these claims was adequately described in the specification,

in the interest of expediting prosecution Claims 65-68 have been canceled rendering the rejection of these claims for lack of written description moot. In addition, Claim 70 has been amended to depend from newly amended Claim 69. In view of these amendments, Applicants request withdrawal of the written description rejection.

Rejections Under 35 U.S.C. §112, First Paragraph- Enablement

The Examiner has rejected Claims 65-68 and Claim 70 for lack of enablement. While Applicants believe the subject matter of these claims was adequately enabled, in the interest of expediting prosecution Claims 65-68 have been canceled rendering the rejection of these claims for lack of enablement description moot. In addition, Claim 70 has been amended to depend from newly amended Claim 69. In view of these amendments, Applicants request withdrawal of the written enablement rejection.

Rejections Under 35 U.S.C. §102(b)

The Examiner has rejected Claims 65-67 and Claim 70 as being anticipated by GenPept Accession Number S15004. Applicants note Claims 65-67 have been canceled rendering this rejection moot. Additionally, Claim 70 has been amended to depend from newly amended Claim 69 and is therefore not anticipated by GenPept Accession Number S15004. Applicants therefore request withdrawal of the 102(b) rejection.

Rejection Under the Judicially-created Doctrine of Obviousness-Type Double-Patenting

The Examiner has rejected Claim 70 as being unpatentable over Claims 1-2 of Frank et al. (US Patent 5,795,862) and Claims 14 and 20-21 of US non-provisional Patent Application 10/271,344. Similarly, the Examiner has rejected Claims 65 and 70 as being unpatentable over Claims 1 and 4 of Frank et al. (US Patent 5,646,115). Applicants note Claim 65 has been canceled. In addition, Claim 70 has been amended to depend from newly amended Claim 69. Since SEQ ID NO:62 (the subject matter of the instant claims) differs from SEQ ID NO:25 and SEQ ID NO:35 (the subject matter of the cited prior art), Applicants believe the subject matter of the instant claims is

distinct from that of the cited prior art. In view of this, Applicants request withdrawal of the obviousness-type double patenting rejections.

Conclusion

Applicants believe the instant claims to be in condition for allowance. In light of the amendments and remarks above, Applicants request the withdrawal of all rejections and solicit allowance of instant claim set. To expedite the allowance of the claims, the Examiner is encouraged to contact the undersigned at (303) 863-9700 should any issues remain.

Respectfully submitted,

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